

## REMARKS

Claims 1-40 are pending in the application. Claims 9 and 35-40 have been withdrawn from consideration.

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b) as anticipated by Imran. The Examiner has referred to Figure 1 of Imran as anticipating instant claims 1 and 2.

Claim 1 specifies a triple catheter arrangement with an inflatable balloon coupled to the end of the first catheter and a self-expanding balloon coupled to the distal end of the second catheter. The first catheter extends through the second catheter and the self-expanding balloon and the second catheter extends through the third catheter.

Imran shows a triple catheter arrangement with three inflatable balloons. Each of the three catheters has two lumina, one of which is an inflation lumen. The outermost catheter has a third, aspiration (i.e. suction) lumen. The innermost catheter has a third lumen for a guide wire or for introducing a saline solution.

The first most apparent difference between Imran and claim 1 is that Imran does not teach or suggest the use of a self-expanding balloon. Imran provides a relatively complex

arrangement of multiple lumena in order to inflate each of the three balloons. Such a complex arrangement is not needed in the present invention, in part, because one of the balloons is self-expanding.

Looking again to the language of claim 1, it is specifically provided that "at least one of said second catheter tube and said third catheter tube is adapted to receive and deliver the intravascular drug to the location of said self-expanding balloon." Although the Imran specification is riddled with numbering errors, it can be determined that the second and third catheter of claim 1 correspond in part to Imran's middle and outer catheter. As mentioned above, Imran's outer catheter is provided with an aspiration lumen and is thus not adapted to deliver an intravascular drug to the location of a self-expanding balloon. Imran's middle catheter has only two lumena, one of which is adapted to inflate its balloon and the other of which is only adapted to receive the innermost catheter. Thus, neither of the lumena are adapted to deliver an intravascular drug without substantial modification. Even if the middle catheter of Imran were modified, it could not deliver the drug to the location of a self-expanding balloon. The only catheter in Imran which is adapted to deliver any kind of fluid into the blood vessel is the innermost catheter which carries the patient's own blood and saline, neither of which are a drug and neither of which are delivered to the location of a self-expanding balloon.

For the foregoing reasons, claim 1 cannot be anticipated by Imran. Moreover, there is nothing in Imran to suggest modification to use a self-expanding balloon or to adapt any of the catheters to deliver a drug to the location of the self-expanding balloon. To the extent that Imran describes a relatively complex arrangement of lumina and inflatable balloons, Imran actually teaches away from the invention of claim 1.

All of the remaining claims stand rejected under 35 U.S.C. §103(a) as obvious over Imran in view of Wolinsky<sup>1</sup> or Leone. The Examiner's rejection states that Imran does not disclose the use of infusion balloons having pores. However, the use of infusion balloons is known from Wolinsky and Leone. The rejection concludes that it would have been obvious to modify Imran with an infusion balloon "in order to enhance the infusion accuracy of medications...". Thirty claims are rejected in two short paragraphs discussing balloons with infusion pores. These thirty claims contain many other limitations which have not been addressed in the Examiner's rejection. Thus, it is impossible for the Applicant to understand the rejection and properly respond to

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<sup>1</sup>The Wolinsky et al. reference was not included with the office action and was not listed on the Notices of References Cited form. A search of the PTO website indicated many patents with an inventor named Wolinsky. After reviewing the list, it was assumed that the Examiner is referring to U.S. Patent Number 5,087,244.

it. For this reason, any continued rejection of the claims not addressed in the present office action, cannot be made final.

Before turning to the specific claims, it should be noted that the stated incentive for modifying Imran doesn't make sense. Since Imran is not concerned with delivering medication, it is unlikely at best that someone would be tempted to modify Imran to enhance the infusion accuracy of medications. Furthermore the secondary references do not address the self-expanding balloon missing from Imran but present in claim 1.

Claim 3 relates to a porous balloon which is the subject of the Examiner's rejection, but is not obvious for the reasons stated above.

Claim 4 relates to pores in the catheter which the Examiner has not addressed.

Claim 5 relates to the third catheter adapted to deliver the drug. This has not been addressed by the Examiner and as discussed above, the third catheter in Imran is adapted to aspirate.

Claim 6 refers to catheter locking means which the Examiner has not addressed.

Claim 7 refers to the first catheter receiving the drug which the Examiner has not addressed.

Claim 8 refers to the second catheter delivering the drug which the Examiner has not addressed.

Claim 10 includes a drug dispenser adapted to automatically dispense the drug as the catheter is moved through a blood vessel. This has not been addressed by the Examiner.

Claim 11 further defines the drug dispenser and has not been addressed by the Examiner.

Claim 12 describes the drug dispenser as including a gear coupled to a plunger, a spool coupled to the gear, and a filament, ribbon, or cable coupled to the spool. None of this has been addressed by the Examiner.

Claim 13 describes the drug dispenser as including means for coupling it to a patient's limb. This has not been addressed by the Examiner.

Claim 14 further defines the drug dispenser and has not been addressed by the Examiner.

Claim 15 is an independent claim directed to a catheter having an automatic drug dispensing means. This has not been addressed by the Examiner.

Claim 16 further defines the drug dispenser and has not been addressed by the Examiner.

Claim 17 describes the drug dispenser as including a gear coupled to a plunger, a spool coupled to the gear, and a filament, ribbon, or cable coupled to the spool. None of this has been addressed by the Examiner.

Claim 18 describes the drug dispenser as including means for coupling it to a patient's limb. This has not been addressed by the Examiner.

Claim 19 further defines the drug dispenser and has not been addressed by the Examiner.

Claim 20 is an independent claim which relates to the first catheter or the self-expanding balloon containing pores. The Examiner has not addressed the self-expanding balloon nor has he addressed pores in a catheter.

Claim 21 describes the self-expanding balloon as comprised of spring wires and a thin membrane coupled to said spring wires. These features have not been addressed by the Examiner.

Claim 22 describes the self-expanding balloon as having an abrasive outer surface. This has not been addressed by the Examiner.

Claim 23 further describes the self-expanding balloon and has not been addressed by the Examiner.

Claim 24 is an independent claim directed to a two catheter system with a self-expanding balloon having an abrasive surface.

Claim 25 states that at least one of said first catheter tube and said self-expanding balloon includes pores. Neither of these features has been addressed by the Examiner.

Claim 26 is an independent method claim which includes the step of dispensing a sclerosing agent adjacent a balloon. The Examiner has not addressed this claim.

Claim 27 includes the step of partially removing the catheter from the varicose vein via the incision with the balloon expanded while continuing said dispensing of said sclerosing agent. This has not been addressed by the Examiner.

Claim 28 further defines the method including the use of a self-expanding balloon. This has not been addressed by the Examiner.

Claim 29 further defines the method and has not been addressed by the Examiner.

Claim 30 is an independent method claim which includes the step of dispensing the intravascular drug through the first catheter while moving the first catheter from the first location to a second location as the first catheter is at least partially pulled out of the incision. The Examiner has not addressed this claim.

Claim 31 further defines the method and has not been addressed by the Examiner.

Claim 32 further defines the method including the step of dispensing the drug adjacent the self-expanding balloon. This has not been addressed by the Examiner.

Claim 33 further defines the method including dispensing the drug through pores in a self-expanding balloon. This has not been addressed by the Examiner.

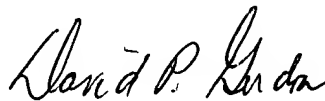


Claim 34 further limits the method and has not been addressed by the Examiner.

In view of the large number of claims not addressed in the office action, an attorney for the Applicant called the Examiner on more than one occasion requesting that a supplemental action be issued. No such action has been received. The Applicant can only conclude that the Examiner has no grounds for rejecting the ignored claims.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "David P. Gordon".

David P. Gordon  
Reg. #29,996  
Attorney for Applicant(s)

65 Woods End Road  
Stamford, CT 06905  
(203) 329-1160

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